seconds. Into a suitable container, accurately weigh out 6 grams of the 50 milligrams per 5 milliliters suspension, or 3 grams of the 100 milligrams per 5 milliliters suspension. Add 5 milliliters of internal standard solution and 25 milliliters of dilution solvent. Shake for 30 minutes using a horizontal platform shaker or equivalent. Centrifuge for about 10 minutes at 3,000 revolutions per minute until the particulate matter has settled. Withdraw a 1 milliliter aliquot of the supernatant and dilute with 1 milliliter of dilution solvent. The sample solutions are stable for at least 48 hours. Refrigeration is not recommended.

(ii) *Calculations.* Calculate the cefpodoxime content as follows:

$$\text{Milligrams of cefpodoxime per 5 milliliters of suspension} = \left(R_{sam}/R_{std}\right)\times\left(W_{std}/W_{sam}\right)\times\left(F_1/F_3\right)\times\left(F_2/F_4\right)\times F_5\times P$$

where:

R_{sam} = Ratio of cefpodoxime proxetil peaks area (sum of both epimers) to the internal standard peak area in the sample preparation;

R_{std} = Ratio of cefpodoxime proxetil peaks area (sum of both epimers) to the internal standard peak area in the standard preparation;

W_{std} = Weight of cefpodoxime proxetil reference standard, in milligrams;

W_{sam} = Weight of sample, in grams;

F_1 = Volume of internal standard used in the sample; preparation, in milliliters;

F_2 = 0.766; The ratio of molecular weight for free-acid cefpodoxime over the molecular weight of cefpodoxime proxetil (427.46/557.61);

F_3 = Volume of internal standard used in the standard preparation, in milliliters;

F_4 = 0.2; Factor to convert to 5 milliliters;

F_5 = Specific gravity of suspension for milligram per 5 milliliter calculated on the air-free basis (specific gravity is determined on a sample of suspension that has been shaken gently on a platform shaker under vacuum for 2 hours); and

P = Purity of the cefpodoxime proxetil reference standard, expressed as a decimal.

(2) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter, except dry the sample at a temperature of 80° C and a pressure of 5 millimeters of mercury or less for 16 hours.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the drug constituted as directed in the labeling.

(4) *Identity.* Using the high-performance liquid chromatographic procedure described in paragraph (b)(1) of this section, the retention times for the peaks of the active ingredients must be within 2 percent of the retention times for the peaks of the corresponding reference standards.

[60 FR 58233, Nov. 27, 1995]

§ 442.180 Cefprozil oral dosage forms.

§ 442.180a Cefprozil tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefprozil tablets are composed of cefprozil and one or more suitable and harmless diluents, binders, lubricants, colorings, and coating substances. Each tablet contains cefprozil equivalent to either 250 milligrams or 500 milligrams of anhydrous cefprozil. The cefprozil content of the tablets is satisfactory if it is not less than 90 percent nor more than 120 percent of the number of milligrams of anhydrous cefprozil that it is represented to contain. The moisture content of the tablets is not more than 7 percent. The tablets pass the dissolution test. The tablets pass the identity tests. The cefprozil used conforms to the standards prescribed by § 442.80(a)(1) of this part.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The cefprozil used in making the batch for potency, E-isomer ratio, moisture, pH, crystallinity, and identity.

(B) The batch for content, moisture, dissolution, and identity.